

Serial No.: 10/761,717
Attorney Docket No.: 291-0002US
Response to Restriction

Remarks/Arguments

The Examiner restricted the claims into four groups.

Group I includes claims 1-16, which are directed to methods of producing insulinotropic GLP-1(7-36) polypeptides and/or GLP-1 analogs.

Group II includes claims 17-18, which are directed to GLP-1(7-36) polypeptides and/or GLP-1 analogs.

Group III includes claims 19-26, which are directed to methods of producing an expression vector comprising multiple tandem copies of a gene encoding a desired polypeptide.

Group IV includes claims 27-36 which are directed to methods of producing insulinotropic polypeptides.

The Applicant hereby elects prosecution of the Group I claims, i.e., claims 1-16, with traverse. If need be, non-elected claims will be pursued in a divisional application to be filed prior to the issuance or abandonment of this application.

Applicant respectfully traverses the election requirements put forth by the Examiner for the following reasons:

Restriction between Groups I and II

The Examiner has noted that Invention I and Invention II are related as process of making and product made. However, the Examiner has found that Groups I and II claim distinct inventions because either the product as claimed can be made by another and materially different process, to wit, by traditional chemical synthesis. However, claim 17 specifically recites a "GLP-1 (7-36) polypeptide and/or GLP-1 analog produced according to the method of claim 1." Claim 18 is dependent on claim 17. Thus, it is respectfully argued that the restriction between groups I and II is improper and that these groups, at a minimum, should be examined together. Furthermore, although this application was not made under 35 USC §371, it is noted that there was no lack of unity found in the underlying PCT application as to claims 1 - 16 as distinct from claims 17 - 18.

Restriction between Groups I and IV

The Examiner has found that Inventions I and IV are directed to "patentably distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint treatment outcome. Therefore, each method is patentably distinct."

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However, a proper restriction requires that there be a serious burden on the Examiner if restriction is not required. *See MPEP 803.I.(B)*. Here, Groups I and IV are both methods of producing an insulinotropic polypeptide. Furthermore, the Examiner has identified near identity of the art groups that would be searched between Groups I and III. Therefore, it is respectfully urged that restriction between Groups I and IV is improper as constituting no undue burden.

Restriction between Groups I and III

The Examiner has found that Inventions I and III are directed to "patentably distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint treatment outcome. Therefore, each method is patentably distinct." However, a proper restriction requires that there be a serious burden on the Examiner if restriction is not required. Here, the Examiner has identified only a single additional subclass of class 435 that may be required to search respective to the invention of group III. Therefore, it is respectfully urged that restriction between Groups I and III is improper as constituting no undue burden.

Additional Elections

To the extent, that further elections are requested for purposes of facilitating examination and that the restriction requirement as to Group IV is deemed improper as argued, Applicant hereby responds to the election requirement, with traverse, as follows:

In Group IV, claim 28, the agent of enzymatic cleavage by alkaline proteases is elected, with traverse. A proper restriction requires that there be a serious burden on the Examiner if restriction is not required. Here, it is respectfully urged that an undue examination burden is not placed on the Examiner in considering patentability of the step of fusion protein cleavage by chemical versus enzymatic treatment, particularly in light of the sufficiently few members of the Markush group. Claims that Applicant believes to be readable on the elected species include pending claims 28 - 31. Applicant requests examination of the generic claims in the listed claim set should more narrow claims to the elected compounds be found patentable.

In Group IV, claim 32, if the election is properly understood to be between the polypeptide sequences of SEQ ID NO: 1 - 18 and exendin-4 analogs, the polypeptides of SEQ ID NO: 1- 18 are elected with traverse. A proper restriction requires that there be a serious burden on the Examiner if restriction is not required. Here, it is respectfully urged that an undue examination

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burden is not placed on the Examiner in considering patentability of related GLP polypeptides of SEQ ID NO: 1 - 18 in addition to exendin-4 analogues, particularly in light of the sufficiently few members of the Markush group of sequences and in accordance with the provisions providing relief to the biotechnology industry of MPEP §803.04. Claims that Applicant believes to be readable on the elected species include pending claims 27 - 36. Applicant requests examination of the generic claims in the listed claim set should more narrow claims to the elected compounds be found patentable.

It is not believed that any further fees are required but should additional fees be required for the consideration of this submission please consider this a request for consideration under the appropriate rule and an authorization for the Assistant Commission to charge and/ or credit Deposit Account No. 50-1922 should any additional fees be required or overpayment made.

Respectfully submitted,



Marilyn M. Huston, Reg. No. 37,851
WONG CABELLO LUTSCH RUTHERFORD & BRUCCULERI, LLP
20333 SH 249, Suite 600
Houston, Texas 77070
Direct (832) 446-2421
Facsimile (832) 446-2424
wcpatent@counselip.com

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Marilyn M Huston